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#13

OCT 24 1989

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New Brunswick, NJ 08933-7003

Re: Patent Term Extension
Application for
U.S. Patent No. 4,219,559
Issued August 26, 1980

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,219,559, issued August 26, 1980 is eligible for patent term extension under 35 USC 156. The period of extension has been determined to be 2 years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register on April 10, 1989 as follows:

$$\begin{aligned}\text{Period} &= 1/2 (\text{Testing Phase}) + \text{Approved Phase} \\ &= 1/2 (1579) + 1404 \\ &= 2194 \text{ days}\end{aligned}$$

Since the regulatory review period took place after the patent issue date and there was no determination of a lack of due diligence, the entire period has been considered. The exception of 35 USC 156(c)(3) does not operate to reduce the period determined above. However, the limitation of 35 USC 156(g)(6)(C) applies in the present situation because Patent No. 4,219,559 was issued August 26, 1980 before the date of enactment (September 24, 1984) of 35 USC 156; the date of exemption under Section 505(i) of the Federal Food, Drug and Cosmetic Act involving Hismanal became effective (October 31, 1980) was before the date of enactment, and the product was not approved for commercial marketing or use (December 29, 1988) before the date of enactment. Since the period of extension calculated under 35 USC 156(c) for Patent No. 4,219,559 and Hismanal cannot exceed two (2) years under 35 USC 156(g)(6)(C), the period of extension will be for two (2) years.

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of U.S. Patent 4,219,559 may be made if filed within one (1) month of the

date of this notice. This period is not subject to an extension of time under 37 CFR 1.136(a). In the absence of such request, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,219,559 a certificate of extension, under seal, for a period of 2 years. The rights derived from the patent during the period during which the patent is extended are defined in 35 USC 156(b).

Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent 4,219,559, granted August 26, 1980 to
Frans Janssens et al
Owner of Record: Janssen Pharmaceutical N.V.
Title: N-HETEROCYCYL-4-PEPERIDINAMINES
Classification: 514-322
Product Trade Name: Hismanal
Term Extended: 2 years

C.E. Van Horn
Charles E. Van Horn
Patent and Trademark Office

cc: Ronald L. Wilson, Director	RE: Hismanal
Health Assessment Policy Staff	FDA Docket # 89E-0085
Office of Health Affairs	
Food & Drug Administration	
5600 Fishers Lane	
Rockville, MD 20857	